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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,294	03/22/2004	Scott R. Presnell	99-106C1	2898

10117 7590 10/14/2008

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
10/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/806,294	**Applicant(s)** PRESNELL ET AL.	
	Examiner GYAN CHANDRA	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12 and 14*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continued sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Robert Landsman/
Primary Examiner, Art Unit 1647

Continuation of 11 does not place the application in condition for allowance because:

Claim 12 is amended.
Claim Rejections – maintained
Claim Rejections - 35 USC § 112
The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 14 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on pages 3-5 of the Office Action mailed 4/15/2008 because the specification, while being enabling for a polypeptide of SEQ ID NO: 1 (Zcyto18), does not reasonably provide enablement for a method of detecting activated CD3+ T-cells in a patient suffering from inflammation, comprising: obtaining a tissue or biological sample from a patient; labeling a polynucleotide, visualizing the labeled polynucleotide in the tissue or biological sample; and comparing the level of labeled polynucleotide hybridization in the tissue or biological sample from the patient to a normal control tissue or biological sample, wherein an increase in the labeled polynucleotide hybridization to the patient tissue or biological sample under highly stringent conditions; relative to the normal control tissue or biological sample is indicative of activated CD3+ T-cells in the patient for the reasons of record on pages 3-5 of the office action of 4/15/2008.

Applicants argue (page 5 of the Response) that the amended claim 12 is now drawn to a method of detecting activated CD3+ T-cells wherein a polynucleotide recited in parts (a)-(d) will hybridize to a complementary sequence in the tissue or biological sample under highly stringent conditions.
Applicants' arguments have been fully considered but they are not persuasive becaue the specification on page 29 defines " highly stringent washing condition" which encompasses typical condition such such as temperatures of about 50-65 C and a wsh solution comprising 0.1-0.2x SSC with 0.1% SDS. It is noted that the specification uses the term "typical condition" which is similar to the term "such as" which does not define what the exact hybridization conditons and wash conditions are. This is very broad definition of "highly stringent condition" and simply using the claimed fragments of SEQ ID NO:1 in a highly stringent hybridization assay does not guarantee that the increase in hybridization signal is due to hybridizing to SEQ ID NO:1. Non-activated T-cells may also express increased levels of other polynucleotides in other circumstances. Applicants may want to put the exact hybridization and wash conditions in the claim. Given the instant methods, it is not clear that Applicants are able to identify an increase specifically in SEQ ID NO:1 and conclude that this hybridization is due to an activated T-cell. Therefore, it is unpredictable how one of the skill in the art can practice the instantly claimed invention and that undue experimentation would be required to practice the invention as broadly claimed. It was suggested to Applicants in the previous Advisory mailed on 7/9/2008 that Applicant can narrow the breadth (without adding new matter) that the sample or tissue used should at least contain CD3+ T-cells (something like: wherein said sample or tissue contain CD3+ T-cells), though this, in itself, may not be sufficient to overcome the rejection.